REMARKS

Claims 1-20 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 as follows:

I. Claim(s) 1-5, drawn to an isolated nucleic acid molecule.

II. Claim(s) 6-10, drawn to an isolated polypeptide.

III. Claim(s) 11-14, drawn to a method of modulating expression of bcl-w or a derivative thereof in a mammal using an antisense molecule.

IV. Claim(s) 15-17, drawn to a method of modulating expression of bcl-w or a derivative thereof in a mammal using an antibody.

V. Claim(s) 18, drawn to a pharmaceutical composition comprising Bcl-W or a derivative thereof or a modulator of Bcl-w activity.

VI. Claim(s) 19-20, drawn to an antibody.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents five separate and distinct inventions. The Examiner has specifically alleged that the claims of Groups I-VI do not relate to a single general inventive concept as they allegedly lack the same or corresponding special technical features. Specifically, the Examiner has asserted that:

> "The isolated nucleic acid, polypeptide and antibody are distinct from each other because they have different uses. The method of modulating bcl-w expression by an antisense molecule have different mode of operation than the method of modulating bcl-w by an antibody. The pharmaceutical composition comprising bcl-w or modulator of

> bcl-w activity requires the therapeutic effect of the composition which is distinct from the above-mentioned invention. Thus, the inventions are mutually exclusive and are of separate uses."
>
> August 2, 1999 Office Action, p. 2, last paragraph to p. 3, line 2.

As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-5, directed to a nucleic acid molecule.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more <u>independent and distinct</u> inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent <u>and</u> distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Under

37 C.F.R. §1.475(a), "unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." It is respectfully submitted that the *bcl-w* gene and its gene product constitute a special technical feature which defines a contribution over the prior art and thus satisfies the requirements for unity of invention.

Under 37 C.F.R. §1.47(b) an application will be considered to have unity of invention if the claims are drawn only to one of the categories listed thereunder. One of the categories under 37 C.F.R. §1.475 is a product and a use of said product. It is respectfully submitted therefore, that the six groups of claims the Examiner has identified represent no more than three sets of products and corresponding uses of said products. For example, the claims of Group I, directed to an isolated nucleic acid molecule relate to a product while the claims of Group III, directed to a method of modulating expression of BCL-w or a derivative thereof in a mammal using an antisense molecule, relate to use of the product. Similarly, the claims of Group II, directed to an isolated polypeptide, relate to a product while the claims of Group V, directed to a pharmaceutical composition, relate to use of the product. The claims of Group VI, directed to an antibody

relate to a product while the claims of Group IV, directed to a method of modulating expression of BCL-w or a derivative thereof in a mammal using an antibody, relate to use of the product in a pharmaceutical composition. Thus, according to 37 C.F.R. §1.475, the claims of Groups I and III should be examined together as should the claims of Groups II and V, and the claims of Groups IV and VI. Thus, at the very least, the claims of Groups I and III, the claims of Group II and V, and the claims of Group IV and VI are very clearly interrelated and interdependent, not "independent and distinct."

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential

limitation of an applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional applications or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) the court held that

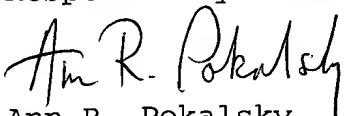
§121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicants' legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims or at least rejoin Claims 1-5 with

Claims 11-14, rejoin Claims 6-10 with Claim 18, and rejoin Claims 15-17 with Claims 19-20.

Respectfully submitted,



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